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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/428,692	10/28/1999	DANIEL B. CARR	2004117-0002	4992

7590 09/23/2003

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EXAMINER

LANDSMAN, ROBERT S

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 09/23/2003

21

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/428,692

Applicant(s)

CARR ET AL.

Examiner

Robert Landsman

Art Unit

1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,29-33,45-49,57-59,62-64,70-74,86-90 and 98-100 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1,29,30,46-48,58,59,62,63,70,71,87-89,99,100 is/are allowed.
- 6) ☒ Claim(s) 31-33,45,49,57,72-74,86,90 and 98 is/are rejected.
- 7) ☒ Claim(s) 2 and 64 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 1.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. Formal Matters

- A. The Information Disclosure Statement, filed 6/24/03, has been entered into the record.
- B. Amendment D, filed 6/24/03, has been entered into the record.
- C. Claims 1, 2, 29-33, 45-49, 57-59, 62-64, 70-74, 86-90 and 98-100 are pending and are the subject of this Office Action.
- D. All Statutes not found in this Office Action can be found, cited in full, in a previous Office Action.

2. Note

- A. Currently, the only opioid binding moiety being examined is SEQ ID NO:3, which is 4 amino acid residues. Therefore, as stands, no amino acids can be “deleted” as seen, for example, in claim 31 since the moiety is already 4 residues in length. This may or may not be an issue, depending on which SEQ ID NOs, if any, are recombined upon allowance.

3. Claim Objections

- A. Claim 69 has been omitted from Amendment D. It is not clear if this claim was intended to be cancelled, or if it was inadvertently omitted.
- B. Claim 2 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 2 is an intended use. However, the peptide is the same and does not further limit claim 1, which already states that the peptide must induce analgesia. Similarly, claim 64 fails to further limit claim 62.

4. Claim Rejections - 35 USC § 112, first paragraph – scope of enablement

- A. Claims 31-33, 45, 49, 57, 72-74, 86, 90 and 98 remain rejected under 35 USC 112, first paragraph, for the reasons already of record on pages 3-4 of the Office Action dated 3/18/03 because the specification, while being enabling for known opioid and SP agonists, such as SEQ ID NO:3, 21 and the endomorphins, does not reasonably provide enablement for any and all “derivatives” having one or more amino acid substitutions, additions, or deletions. The specification does not enable any person skilled in

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the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Applicants argue that the level of skill in the art of peptide chemistry was quite high at the time of the invention and that structure-activity studies revealing neuropeptide structure characteristics for maintaining functionality, as well as methods of assaying compounds, were also available at the time. These arguments have been considered, but are not deemed persuasive.

First, the breadth of the claims is excessive with regard to Applicants' claiming all chimeric peptides which comprise opioid and SP derivatives. As worded, these moieties can have every amino acid altered in some way, including an unlimited number of additions. Furthermore, due to the fact that these moieties can comprise one or more substitutions, the claimed moieties do not have to have any amino acid residues in common with SEQ ID NO:3 or 21. Therefore, any conceivable opioid or SP agonist moiety would be encompassed by the claims. Applicants have only provided guidance and working examples of those moieties disclosed in Tables 1 and 4 of the specification and have not provided any guidance or working examples of any and all opioid or SP agonist moieties which can have up to every amino acid residue substituted, or an unlimited number of additions, to SEQ ID NO:3 or 21. Furthermore, it is not predictable to the artisan how to make functional mu opioid or SP agonist moieties other than those disclosed in the specification since the only requirements are that the moieties are agonists of at least 4 residues.

Therefore, in summary, the breadth of the claims is excessive with regard to Applicants claiming all peptide chimeras which comprise opioid and SP moieties of at least 4 residues. Applicants have only provided guidance and working examples of these moieties as seen in Table 1 and 4 of the specification. Given these broad limitations, it is not predictable to the artisan how to make a functional chimera which binds both SP and opioid receptors wherein the only requirement is that these moieties must comprise at least 4 residues. It is believed that all pertinent arguments have been addressed.

B. The rejection of all pending claims under 35 USC 112, first paragraph, which recited that the opioid moiety is other than an agonist, has been withdrawn in view Applicants' amendment to the claims to limit the claims to opioid agonists.

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5. Claim Rejections - 35 USC § 112, first paragraph – written description

A. Claims 31-33, 45, 49, 57, 72-74, 86, 90 and 98 remain rejected under 35 USC 112, first paragraph, for the reasons already of record on pages 4-5 of the Office Action dated 3/18/03. Applicants argue that the claims are perfectly clear to one of ordinary skill in the art in view of the amendments and the specification. This argument has been considered, but is not deemed persuasive.

This genus could include hundreds of opioid and SP moieties. As worded, these moieties can have every amino acid altered in some way, including an unlimited number of additions. Furthermore, due to the fact that these moieties can comprise one or more substitutions, the claimed moieties do not have to have any amino acid residues in common with SEQ ID NO:3 or 21. Therefore, any conceivable opioid or SP agonist moiety would be encompassed by the claims. Applicants have only provided adequate written description of those moieties disclosed in Tables 1 and 4 of the specification and have not adequately described any and all opioid or SP agonist moieties which can have up to every amino acid residue substituted, or an unlimited number of additions, to SEQ ID NO:3 or 21.

B. The rejection of all pending claims under 35 USC 112, first paragraph, which recited that the opioid moiety is other than an agonist, has been withdrawn in view Applicants' amendment to the claims to limit the claims to opioid agonists.

6. Conclusion

A. Claims 1, 29, 30, 46-48, 58, 59, 62, 63, 70, 71, 87-89, 99 and 100 are allowable.

Advisory information


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Landsman whose telephone number is (703) 306-3407. The examiner can normally be reached on Monday - Friday from 8:00 AM to 5:00 PM (Eastern time) and alternate Fridays from 8:00 AM to 5:00 PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4242. Fax draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Robert Landsman, Ph.D.
Patent Examiner
Group 1600
September 22, 2003


ROBERT LANDSMAN
PATENT EXAMINER